IN THE SUPREME COURT

STATE OF ARIZONA

ANDRE LEE JUWAUN MAESTAS, Petitioner, vs. THE HONORABLE DEAN FINK, JUDGE OF THE SUPERIOR COURT FOR THE STATE OF ARIZONA, in and for the County of Maricopa, Respondent Judge, STATE OF ARIZONA, Real Party in Interest.	Arizona Supreme Court No. CV-15-0015-PR Court of Appeals Division One No.1 CA-SA 14-0245 Maricopa County Superior Court No. CR2014-127252-001

BRIEF OF AMICUS CURIAE ARIZONA ARIZONA PROSECUTING ATTORNEYS' ADVISORY COUNCIL IN SUPPORT OF REAL PARTY IN INTEREST

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I. INTEREST OF THE ARIZONA PROSECUTING ATTORNEYS' ADVISORY COUNCIL

The Arizona Prosecuting Attorneys' Advisory Council ("APAAC") respectfully submits this *amicus curiae* brief on behalf of its members, in support of Real Party in Interest, the State of Arizona.

APAAC is a state agency created by A.R.S. § 41-1830 *et seq.* APAAC is comprised of, *inter alia,* the elected county attorneys from Arizona's fifteen counties, in addition to the Arizona Attorney General, and several head city court prosecutors. APAAC's primary mission is to provide training, resources, and a variety of other services to the more than 800 state, county, and municipal prosecutors in Arizona. APAAC also serves as the liaison for prosecutors with the legislature and the courts, advocating for prosecutorial interests before the legislature or proposing changes to this Court's procedural rules.

In its capacity as a state agency, Rule 16(a), Ariz. R. Civ. App. P. specifically permits APAAC to file an *amicus curiae* brief without requiring either consent of the parties or leave of court. Based on its status as a state agency, this Court has accepted *amicus curiae* briefs from APAAC in other cases.

APAAC's interest in this case is to protect public health and safety by ensuring the primacy and effectiveness of this nation's comprehensive regulatory system for medicine delivery, which is designed to ensure consumer safety and minimize illicit drug trafficking and substance abuse.

APAAC seeks resolution of the constitutional conflict between the Arizona Medical Marijuana Act ("AMMA"), A.R.S. § 36-2801 et seq., and the federal statutes regulating drug distribution, specifically the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq. APAAC has read the relevant briefs and offers an important analysis beyond what has been presented.

II. ARGUMENT

The Federal Government has crafted an intricate and comprehensive scheme for the safe, effective delivery of medicine to Americans. As described throughout this Brief, the AMMA is fundamentally incompatible with that scheme. That incompatibility goes far beyond marijuana merely being a banned substance under Federal law and partially decriminalized under Arizona law. Instead, the AMMA sets up a contrary system that is incompatible with the Federal scheme. The two cannot coexist, so the AMMA is preempted.

A. The Comprehensive Federal Regulatory Scheme

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act ("CDAPCA"). CDAPCA includes the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq.

"The FDCA's comprehensive scheme of drug regulation is designed to ensure the nation's drug supply is safe and effective." *U.S. v. Sage Pharmaceuticals, Inc.*, 210 F.3d 475, 479 (5th Cir. 2000) (citation omitted). Similarly, "the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, and in what manner." *Gonzales v. Raich*, 545 U.S. 1, 27, 125 S. Ct. 2195, 2211 (2005). The Food and Drug Administration ("FDA"), this nation's preeminent drug

regulatory body, supports the federal scheme through its mission to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect the public health … by ensuring human and veterinary drugs are safe and effective." 21 U.S.C. § 393.

The federal system identifies drugs with a potential for abuse and labels them "controlled substances." 21 U.S.C. §§ 811–812. The system categorizes drugs into five "schedules" based on their potential for abuse and other factors. *Id.* § 812. Schedule I drugs have "high potential for abuse," lack "currently accepted medical use in treatment in the United States" and "lack accepted safety for use of the drug or other substance under medical supervision." *Id.* § 812 (b)(1). The other schedules of drugs have lesser potential for abuse and greater medical value. *Id.* § 812.

Schedule I drugs are not approved for medical use. Schedule II – IV drugs can be dispensed only with a physician's prescription, and Schedule V drugs are over-the-counter. 21 U.S.C. § 829. Further, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04.

Marijuana and its active ingredients in most forms are Schedule I drugs, and

thus banned from any medical use. 21 U.S.C. § 812. The CSA provides an ongoing process to reevaluate controlled substances and determine whether to transfer them among schedules or decontrol them by removing them from all schedules. 21 U.S.C. § 811(a). The CSA also provides for the scheduling of new substances. *Id.*

A drug's scheduling is determined through rigorous medical and scientific evaluation. 21 U.S.C. §§ 811–12. All persons who handle controlled substances, such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies and scientific researchers, must register with the Drug Enforcement Administration ("DEA"). 21 U.S.C. § 823. Registrants must maintain detailed records of their respective controlled substance inventories, as well as establish adequate security controls to minimize theft and diversion. 21 C.F.R. § 1304.11(a).

A manufacturer intending to market a new drug must go through a rigorous process. 21 U.S.C. § 355. The sale of drugs before they have been approved through that process is prohibited. *Id.* A drug application can be rejected if the evaluation of the drug does not show "whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* § 355(d).

B. Marijuana's place in federal law

As a Schedule I drug, marijuana "may be obtained and used lawfully only by

doctors who submit a detailed research protocol for approval by the Food and Drug Administration and who agree to abide by strict recordkeeping and storage rules." *Americans for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438, 441 (D.C. Cir. 2013) (citation omitted.)

"When it enacted the CSA in 1970, Congress placed marijuana in Schedule I. From that time, petitioners have indefatigably sought to obtain a change in marijuana's classification." *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 930 F.2d 936, 937 (D.C. Cir. 1991). But the DEA, FDA and NIDA [National Institute on Drug Abuse] have, in study after study, reached the same conclusion: marijuana continues to meet the criteria for Schedule I control under the CSA because "(1) Marijuana has a high potential for abuse. (2) Marijuana has no currently accepted medical use in treatment in the United States. (3) Marijuana lacks accepted safety for use under medical supervision." Drug Enforcement Administration, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552, 40567 (July 8, 2011); *see also Raich*, *supra,* 545 U.S. at 15 n.23, 125 S. Ct. 2195, 2204 n.23 (describing efforts to reschedule marijuana).

C. The AMMA

The AMMA is profoundly different from and incompatible with the carefully crafted federal scheme for safe delivery of medicine. The AMMA

authorizes "qualifying patients" with "debilitating medical conditions" to possess marijuana for "medical use" pursuant to a state-issued card. A.R.S. §§ 36-2801 (9), (13), 36-2804.02. The term "medical use" is broadly defined:

> "Medical use" means the acquisition, possession, cultivation, manufacture, use, administration, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered qualifying patient's debilitating medical condition or symptoms associated with the patient's debilitating medical condition.

A.R.S. § 36-2801(9). The AMMA also includes broad "findings" that marijuana is medically useful. A.R.S. § 36-2801, Historical and Statutory Notes Sec. 2 ("findings" portion of 2010 Proposition 203).

The AMMA creates "a presumption that a qualifying patient or designated caregiver is engaged in the medical use of marijuana pursuant to [Title 36, Chapter 28.1]." A.R.S. § 36-2811(A). Qualifying patients, designated caregivers, and others who participate in the distribution of marijuana under the AMMA are protected from arrest and other penalties, both civil and criminal. A.R.S. § 36-2811. Many of the records relating to cardholders and dispensaries are deemed confidential. A.R.S. § 36-2810.

The AMMA specifies a procedure for qualifying patients to obtain marijuana. The prospective qualifying patient must first apply to the Department of Health Services for a registry identification card. A.R.S. § 36-2804.02. That application includes a "written certification issued by a physician," as well as an

application fee and personal information about the applicant. *Id.* The "written certification" must include a physician's opinion that "the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition." A.R.S. § 36-2801(18).

Physicians may only issue a written certification "in the course of a physician-patient relationship after the physician has completed a full assessment of the qualifying patient's medical history." *Id.* Notably, however, the written certification does not purport to be and is not a prescription under federal law. The term "physician" under the AMMA is broadly used to include naturopathic and homeopathic physicians. A.R.S. § 36-2801.

The AMMA provides for registration of dispensaries and their agents. A.R.S. §§ 36-2804, 36-2804.01. Dispensaries are subject to a number of statutory requirements, including only being allowed to transfer marijuana to qualifying patients and having certain security requirements. A.R.S. § 36-2806. Dispensaries may cultivate unlimited amounts of marijuana "to assist registered qualifying patients with the medical use of marijuana directly or through the registered qualifying patients' designated caregivers." A.R.S. § 36-2806(D). Under certain circumstances, qualifying patients and designated caregivers can also grow up to twelve marijuana plants each. A.R.S. § 36-2801(1).

D. Preemption Law

Congress has the power to preempt state law under a variety of circumstances. *See Arizona v. United States*, 567 U.S. ___, 132 S. Ct. 2492, 2500–01 (2012). Most relevant to the AMMA are "those instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 2501 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 404 (1941)).

"What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373, 120 S. Ct. 2288, 2294 (2000). "'If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.'" *Id.* (citations omitted). A state law can be preempted if it "interefere[s] with the careful balance struck by Congress" even if it "attempts to achieve one of the same goals as federal law." *Arizona*, 132 S. Ct. at 2505.[1]

[1] *Arizona v. United States* involved the preemption of Arizona's S.B. 1070, an immigration law. 132 S. Ct. at 2505. However, the Court's broad holding that portions of S.B. 1070 were preempted because they would "interfere with the careful balance struck by Congress with respect to unauthorized employment of aliens" is equally applicable to the AMMA as it is to immigration. *Id.* Indeed, the

The CSA contains the following preemption clause:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, *unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together*.

21 U.S.C. § 903 (emphasis added). The FDCA similarly provides that: "a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S. Ct. 1187, 1196 (2009) (citation omitted). When measured against the federal framework, the AMMA cannot survive.

E. The AMMA Is Preempted

The AMMA decrees marijuana is "medicine" and allows for its cultivation, distribution and use. Both that fundamental determination and the accompanying procedures are in complete conflict with the federal laws and regulations governing the classification, production, distribution, marketing and use of drugs and medicine in the United States.

The conflict can be highlighted through several examples:

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preempted portion of S.B. 1070 "attempt[ed] to achieve one of the same goals as federal —the deterrence of unlawful employment," but "it involve[d] a conflict in the method of enforcement." *Id.* The AMMA, by contrast, attempts to achieve precisely the *opposite* purpose of the relevant federal laws.

1. The AMMA, by popular vote, classifies marijuana as medicine. By contrast, federal law, based on research and scientific testing, provides that marijuana is a Schedule I drug with "no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812.
2. The AMMA's authorization of marijuana use as medicine subverts the FDCA's purpose to protect the public from unsafe drugs, including the requirement of pre-market approval by the FDA of all medicines for their intended purpose. *See* 21 U.S.C. §§ 355, 393(b). The federal goal is plainly only possible if states cannot independently avoid it.
3. The AMMA's limited inspection and security requirements, and confidentiality requirements, are completely at odds with the CSA's requirement for inventory control and registration of all handlers of controlled substances, including marijuana. *Compare* 21 U.S.C. § 823 *and* 21 C.F.R. § 1304.11(a) *with* A.R.S. §§ 36-2806, 36-2810.
4. The AMMA's process for obtaining written certification from a physician for marijuana stands in stark contrast to the established federal system for obtaining any controlled substance only with a prescription. *Compare* 21 U.S.C. § 829 *with* A.R.S. § 36-2801(18).
5. The AMMA's labeling of marijuana as medicine and approval of its medical use through the ballot box are inconsistent with the federal

scheme's mechanism to reschedule drugs only through specific processes and after extensive scientific study. *See* 21 U.S.C. §§ 355, 811–12.[2]

Ultimately, the AMMA and federal law and policy approach marijuana from two fundamentally different and incompatible directions. The federal system is based on clinical research and science to ensure public safety. Based upon that research, the consistent federal policy is that marijuana lacks acceptable safety for use.

By contrast, the AMMA is a voter declaration that, contrary to federal law, policy and research, marijuana is medically useful and acceptably safe. The AMMA is not how safe medicine delivery in the United States is designed to work. The AMMA "would interfere with the careful balance struck by Congress," and is thus preempted. *Arizona*, 132 S. Ct. at 2505.

In the context of the AMMA and the delivery of medicine, preemption means that states cannot disregard the federal authority that sets nationwide standards. To hold otherwise is to authorize a national quilt of different legal regimes in each state, undermining this nation's deep-rooted interest in ensuring

[2] The facts of this case suggest a further potential conflict. If Petitioner is correct that AMMA is so broad that medical marijuana may never be criminally prohibited on university campuses, it is possible that universities could not even adopt policies prohibiting the use of medical marijuana. *See* A.R.S. § 36-2811(B) (describing broad immunities for registered qualified patients). If this Court were to adopt such a broad construction of the AMMA, universities could run afoul of federal funding requirements conditioned on the prohibition of marijuana.

the safety of our drug supplies.

III. CONCLUSION

As described herein, the AMMA is inconsistent with federal policy regulating the manufacture, distribution, prescription and use of drugs within the United States. It is therefore preempted. Accordingly, APAAC respectfully requests that this Court decline review of this case. If this Court grants review, APAAC respectfully requests that this Court expressly hold that the AMMA is preempted.

DATED this 10th day of March, 2015.

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of March, 2015, the *Amicus Curiae* Brief of the Arizona Prosecuting Attorneys' Advisory Council was electronically filed with the Clerk of the Arizona Supreme Court, using that Court's electronic filing system.

On this date a copy of the *Amicus Curiae* Brief was served electronically to the email addresses noted, and served by first-class mail, addressed to:

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CERTIFICATE OF COMPLIANCE

Under Rule 6(c) and Rule 23(c) of the Arizona Rules of Civil Appellate Procedure, I certify that the attached Brief uses proportionately spaced type of 14 points or more, is double-spaced using a roman font, and contains 3129 words.

DATED this 10th day of March, 2015.

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